

**From:** May, David  
**Sent:** Thu, 6 Oct 2016 14:09:25 -0400 (EDT)  
**To:** St. John, Kimberly[kstjohn@amerisourcebergen.com]  
**Cc:** Gundy, Bruce[BGundy@amerisourcebergen.com]  
**Subject:** Naddi slides.pptm  
**Attachments:** Naddi slides.pptm

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Kim,

Here are my slides. Could you change the format/background to match Bruce's slides and then add to the back of his presentation. Thanks

Bruce,

If you look thru my slides, I have added notes which will be generally reflective what I plan on saying. Are you in tomorrow? Maybe we can run through it quickly after Kim combines to see how it looks all together. DM

PLAINTIFFS TRIAL  
EXHIBIT  
**P-00898\_00001**

# Wholesale Distributors and Diversion Control

## Presentation Goals

In light of this audience, I thought about where I wanted to focus my discussion and there really are two areas. The first, I want to provide you on some general information describing what diversion control programs look like at the wholesale distributor. I do need to offer a caveat here, there are probably around 800 wholesale distributors in the U.S., but the three largest, McKesson, Cardinal and AmerisourceBergen have a combined market share in excess of 90%. I obviously cannot speak to the programs at McKesson and Cardinal but can generally describe what we all do and then be more specific about ABC if you have questions. Second, I want to give you information that can be useful to you in your day to day jobs of investigation potential criminal behavior. If you were paying attention, I've already done that. For example I told you that three wholesalers control in excess of 90% of the market. So if you were investigating a pharmacy and you wanted to gather information about sales of certain controlled substances, you have better than a 90 percent chance of getting that information by issuing a subpoena to all three companies.

## Diversion Control Program

- Know Your Customer Due Diligence
- System to Detect and Report Suspicious Orders
- Continuous Monitoring or Due Diligence
- Training and Education

So, if I were to breakdown the common elements of a wholesalers diversion control program, these would be the four baskets and I'd like to spend a little time talking about each one.

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## Legal Requirement

- **Title 21 - Code of Federal Regulations**
  - **21 CFR 1301.71(a)** – “All applicants and registrants shall provide **effective controls** and **procedures** to guard against theft and diversion of controlled substances.”
  - **21 CFR 1301.74(b)** – “The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances.”

You don't see specific reference to knowing your customer in the law and regulations, but you do see repeated references to the concept in the final decisions and orders issued relative to actions taken by DEA against registrants, as well as in public training sessions by DEA.

AmersourceBergen		Retail Pharmacy Questionnaire	
<p><b>Form will not be for assessment unless all questions are completed</b></p> <p>Name of Retail Pharmacy: _____</p> <p>Phone of Retail Pharmacy: _____</p> <p>Marketing Director's Contact: _____ (Send Self-Reply Permit ID)</p>		<p><b>AmersourceBergen</b></p> <p><b>Retail Pharmacy Questionnaire</b></p> <p>DATE: _____</p> <p>TIME: _____</p> <p>NAME: _____</p> <p>ADDRESS: _____</p> <p>CITY: _____</p> <p>STATE: _____</p> <p>ZIP: _____</p>	
<p><b>SECTION I - General Information</b></p> <p>1. Primary business is in business on the ADA application: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>2. ADA application is for the following business: <input type="checkbox"/> Retail <input type="checkbox"/> Wholesale</p> <p>3. ADA application is for the following business: <input type="checkbox"/> Retail <input type="checkbox"/> Wholesale</p> <p>4. ADA application is for the following business: <input type="checkbox"/> Retail <input type="checkbox"/> Wholesale</p> <p>5. ADA application is for the following business: <input type="checkbox"/> Retail <input type="checkbox"/> Wholesale</p> <p>6. ADA application is for the following business: <input type="checkbox"/> Retail <input type="checkbox"/> Wholesale</p> <p>7. ADA application is for the following business: <input type="checkbox"/> Retail <input type="checkbox"/> Wholesale</p> <p>8. ADA application is for the following business: <input type="checkbox"/> Retail <input type="checkbox"/> Wholesale</p> <p>9. ADA application is for the following business: <input type="checkbox"/> Retail <input type="checkbox"/> Wholesale</p> <p>10. ADA application is for the following business: <input type="checkbox"/> Retail <input type="checkbox"/> Wholesale</p>		<p><b>SECTION II - Financial Information</b></p> <p>1. Total sales for the year ended 12/31/99: \$ _____</p> <p>2. Total sales for the year ended 12/31/98: \$ _____</p> <p>3. Total sales for the year ended 12/31/97: \$ _____</p> <p>4. Total sales for the year ended 12/31/96: \$ _____</p> <p>5. Total sales for the year ended 12/31/95: \$ _____</p> <p>6. Total sales for the year ended 12/31/94: \$ _____</p> <p>7. Total sales for the year ended 12/31/93: \$ _____</p> <p>8. Total sales for the year ended 12/31/92: \$ _____</p> <p>9. Total sales for the year ended 12/31/91: \$ _____</p> <p>10. 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Total sales for the year ended 12/31/10: \$ _____</p> <p>91. Total sales for the year ended 12/31/09: \$ _____</p> <p>92. Total sales for the year ended 12/31/08: \$ _____</p> <p>93. Total sales for the year ended 12/31/07: \$ _____</p> <p>94. Total sales for the year ended 12/31/06: \$ _____</p> <p>95. Total sales for the year ended 12/31/05: \$ _____</p> <p>96. Total sales for the year ended 12/31/04: \$ _____</p> <p>97. Total sales for the year ended 12/31/03: \$ _____</p> <p>98. Total sales for the year ended 12/31/02: \$ _____</p> <p>99. Total sales for the year ended 12/31/01: \$ _____</p> <p>100. Total sales for the year ended 12/31/00: \$ _____</p>	

So you will find that what wholesalers collect a good deal of information from their customers pursuant to the KYC requirement. Of course, what is the take away for you as an investigator, you can access that information pursuant to your investigations. Here is an example of a form that we use at ABC for our new independent retail pharmacies. The form contains all of the basic biographical information you would expect; information about prior disciplinary actions; other distributors who are supplying the customer; anticipated payment methods; business description in terms of specialty practices such as compounding; and information about anticipated purchasing of some of the more high risk controlled substances. ABC also collects photos of the retail pharmacy during the process. You should also know that what we collect in terms of information can and does vary depending upon the customer type. Finally, what do we do with this information. We confirm the content of all of the information provided. We verify valid licensing; search data basis for adverse actions; search for and public news stories; follow up with the customer where we have questions relative to their projecting purchasing. Of course, we also document this information for future requirements, including fulfilling any requests by law enforcement and or regulatory bodies.



## Diversion Control Program

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Identifying and reporting suspicious orders, not only to DEA, but also a handful of states now. Having recently spent close to two years evaluating and updating this program at ABC, I have some personal observations that I'd like to share by way of discussion.

## Legal Requirement

- **Title 21 - Code of Federal Regulations**
- **21 CFR 1301.71(a)** – “All applicants and registrants shall provide **effective controls** and **procedures** to guard against theft and diversion of controlled substances.”
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Unlike the Know Your Customer standard, there is no ambiguity here in terms of the legal requirement imposed upon the distributor registration. So, first point here with my goal of continuing to provide you with information you can use, distributors maintain these records of suspicious orders and you can access them as part of your official investigations. But that also brings me to an opening in terms of discussion. If our common goal is to detect, identify and prevent diversion, I think that a much more effective way of doing that is not by identifying a specific order in time by a customer, but by analyzing and reviewing the ordering behavior by that customer over a period of time. I'm going to talk more about that when I discuss our ongoing monitoring efforts in a couple of minutes.



## Legal Requirement

### ➤ Title 21 - Code of Federal Regulations

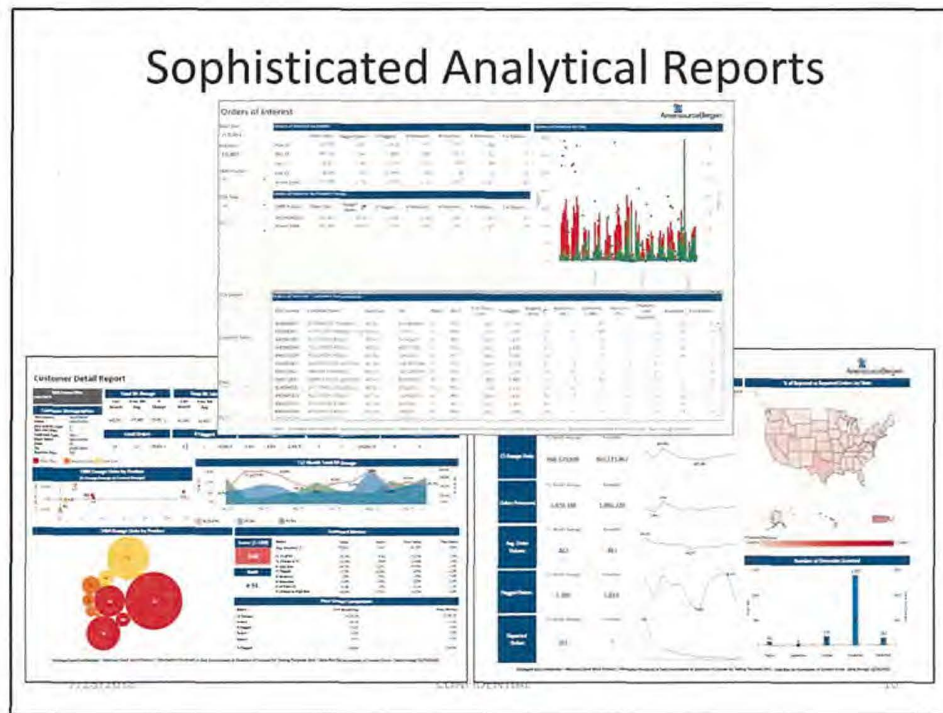
- **21 CFR 1301.74(b)** – “The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”

Looking at the legal requirement in more detail, I wanted to make a couple of points. First, as I said, identifying and isolating a single order and reporting that order has, in my opinion, limited utility in preventing diversion. The requirement was enacted years ago, long before our current prescription epidemic, and was probably more influenced by the diversion of precursor chemicals than prescription drugs. Further, suspicious orders as defined above is pretty ambiguous, of course knowing that some of that is intended. There are other issues here. Lets look at “unusual frequency”. In todays world and the healthcare industry, most of your independent pharmacies are placing orders every single day for next day delivery. By keeping their inventory levels low, they are more able to control their cash flows in a very competitive environment. So that’s one example of the market and industry changing and the need for the regulations to keep pace. To DEA’s credit and the great team that have led by Lou Milione, I think that they are looking at all of these things.

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All of the major wholesalers have programs in place to continually monitor their customer's activities. I think that, in my opinion, this is the area where we can be most effective at curbing potential diversion, because we are looking at our customers and evaluating them holistically over a period of time, as opposed to looking at an isolated order.



We own and manage an incredible amount of data. At ABC, we've developed very powerful tools to analyze our customer ordering behaviors and we use those reports to identify potential red flags. When we do identify those red flags, we engage with the customer to better understand the source of the red flags by better understanding the business. In cases where the red flag behavior persists and we don't receive adequate explanations from our customers, we taken action against the customer, including discontinuing our relationship with the customer, and this is how you more effectively prevent diversion. We do this every day, day in and day out, without input from DEA, state BOPs or and other law enforcement entities. Once we discontinue the relationship with a customer, we add the customer to a Do Not Ship list that we maintain at our company. So, what can you take away from this. I know how difficult it can be to achieve a successful outcome when investigating a Doctor or Pharmacy. If you feel there is a pharmacy, who is a customer of ABC, that may be engaged in illegal behavior, please let us know. We don't want that type of customer and If I here that law enforcement has a concern, I'm going to use all of those analytics and our internal team to follow the process I've described above. That's the commitment we've made to prevent diversion and which I make to all of you.

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All of the major wholesalers have training and education programs. Keeping stakeholders informed and updated on the relevant issues will also contribute to our anti-diversion efforts.

## **Training and Education**

- Customers
  - Trade shows
    - Continuing Education Courses
  - Customer visits and communications
  - Educational materials
- Associates
  - Sales Force
  - Compliance sensitive positions

So, who do we train and educate? Our customers, thru trade shows, location visits and communications. I think there is still a segment of customers who continue to be vulnerable because they lack information. So we will continue to seek opportunities to provide the necessary information. Of course, we train our own associates. At ABC, we have an online general diversion awareness training program that is mandatory for all sales associates before engaging with our customers. I think an area where we can all improve here is the public arena, which I think is terribly lacking in terms of information campaigns relative to prescription drug abuse.





Challenges of the Wholesale Distributor



What percentage of medicines shipped  
are controlled substances

- A. 15%
- B. 22%
- C. 36%
- D. 47%

So, before we talk about the challenges of the wholesale distributor, I have a quick quiz for you. Anyone care to answer?

What percentage of medicines shipped  
are controlled substances

- A. 15%
- B. 22%
- C. 36%
- D. 47%

For the big three wholesalers, its approximately 15%. So the other 85% of the medicines delivered by this incredibly efficient supply chain are your blood pressure meds, cholesterol meds, and life saving specialty drugs for cancer and kidney failure.

## Challenges -Wholesaler

- Ensuring legitimate medical needs are met while preventing diversion
- Large number of orders placed & delivered per day
- Large number of customers
- Resistance by Dispensers to providing information
- Dispensers view multiple wholesalers as a competitive advantage (i.e., shopping for the best price)
- Activities are a snapshot in time
  - Inability to be at dispenser's business 24/7
- Separating Wholesalers' regulatory obligations from Dispensers' regulatory obligations
- Cannot always corroborate information provided by the customer

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So, does everyone recall several months ago the situation in Florida when numerous instances were identified where patients were struggling in getting their prescriptions filled, including veterans and other folks that had experienced traumatic injuries? During that time, one of the criticisms that was leveled was that wholesale distributors were limiting supplies of pain medications. So, this is a real concern and is our biggest challenging, preventing diversion while ensuring our customers can serve their legitimate patients. Another issue, our abilities are restricted in many areas. I don't have subpoena power and cannot compel our customers to produce information. And when they do provide information, I'm not always sure it is accurate. For instance, do they have another supplier that I'm aware of – I have no visibility here.



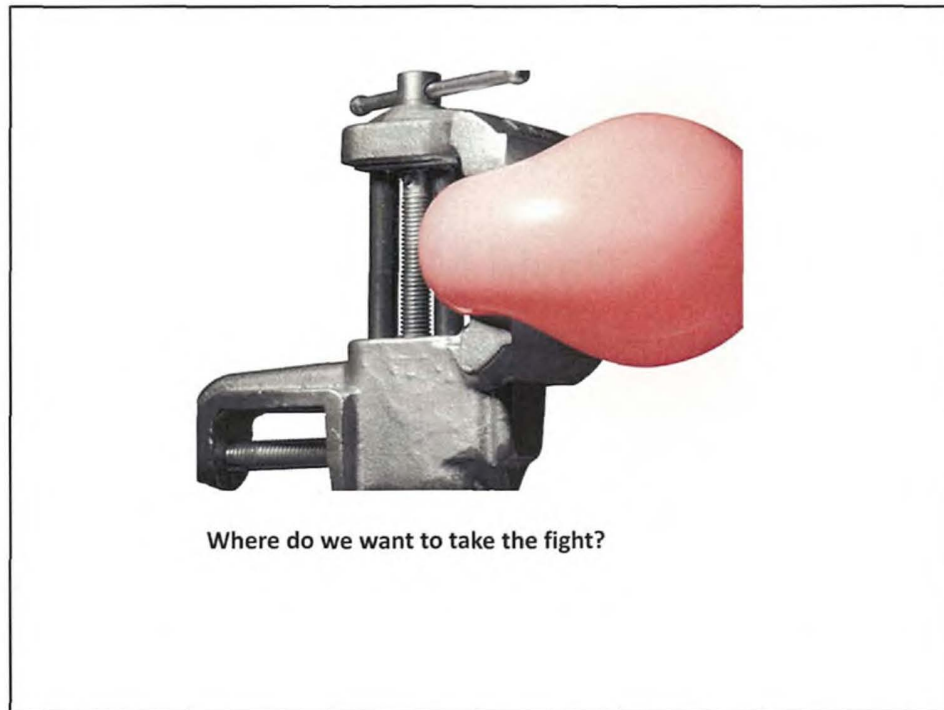
So any of you have attended any DEA briefings have seen this slide, but I wanted to share it to emphasize one point. We all, registrants have regulations and requirements imposed upon us by virtue of role in the system. I truly believe that if we all live up to our individual responsibilities and obligations, we will collectively have a huge positive impact on the prescription abuse issue. On the other hand, any weak links in the system will cause all of us to become less effective. Related to this, depending on the type of registration you hold will cause variations in the requirements. To that end, a wholesaler is responsible for knowing the customer and monitoring the controlled substances and listed chemicals shipped to that customer, rejecting and reporting suspicious orders. What don't we see? We don't see our customers patients; we don't see the prescription nor can we make a clinical determination about the medical legitimacy of the prescription. Nor do we know the practitioners who are writing the prescriptions being filled by our customers. Nor is it necessary if everyone is fulfilling their individual responsibilities.

## Other Challenges – Connecting the Dots

- Previous large-scale diversion schemes were in concentrated areas with highly visible red flags (e.g., long patient lines, out-of-state license plates). Today's red flags are more subtle and dispersed.
- Wholesalers have limited visibility at key areas of the decision-making process
- We do not have access to critical information that connects the dots
  - We cannot see patient level information to determine
    - Distance from patient's residence to the pharmacy
    - Determine pattern prescribing / overprescribing
  - We cannot see information from a State's PMP
- Wholesalers do not practice pharmacy
  - Privacy laws and lack of professional healthcare knowledge (i.e., wholesaler  $\neq$  licensed healthcare professional) limit evaluation of dispenser's activities

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Final point, we must be mindful of our actions in addressing the epidemic of prescription drug abuse. I will use the relationship between prescription opioids and heroin as an example. When I was overseeing the drug task force in Charlotte 10 years ago, there was a rise in the influence of Mexican DTOs in growing the heroin market. The issue was overwhelming and the cross culture of people that were using heroin amazed me. Over the last couple of years, the overall tightening of the prescription opioid market has led to increased heroin abuse. Having confronted both issues, I believe that our chances for success are much better in the public arena working with pharmacists and doctors.



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Thanks, concluding comments.